QA Transition Plan -
Prepared 2/27/07

1. Focus of QA Department will shift
    a. Focus of QA will be centered on systems that are common to all laboratories and ancillary departments. QA will focus less on the daily, weekly, monthly QC for the labs.
    b. These responsibilities will shift to the Technical Supervisors for each lab, as dictated by CLIA. We need to identify the gap in responsibilities that will be created by this shift in focus by the QA Department.
        1. We must confirm that each lab has a Technical Supervisor to perform the duties.
        2. We must review the responsibilities of the Technical Supervisor with the designated Technical Supervisors and provide training/ clarification of expectations as needed.
        3. We must ensure that the QC (daily, new lot, weekly) is being monitored and documented by the Technical Supervisors.
        4. We must ensure that the additional documents currently listed in the "Record Review Schedule" are being monitored and documented appropriately.
        5. We must figure out how to address gaps in review and documentation of reviews until the transition is completed. See recommendation in item #2 below.

2. Recommendation to address gaps in document review until transition is completed:
   The Annual Records Review Schedule will continue to be a part of the QA Program during the transition. This document was distributed to each laboratory during the December, 2006 QA/QC meetings.
    a. The first week of each month, QA will send a global email to all Supervisors and Directors requesting the documents listed for the particular month. These documents should be delivered to the QA Office before the 15th of each month. If the Laboratory Supervisor or Director wants to discuss any of these documents with QA, a meeting time will be set up.

       PLEASE put these documents in a folder or envelope and clearly mark the Lab name and the name of the person who is should receive these back.

    b. QA will log receipt of the documents.

    c. If the documents are not received in the QA Office by the 15th of the month, QA will send an email to the Laboratory Director and Dina Caloggero indicating which records are pending.

3. Please continue to forward the following documents to QA:
    a. CLIA paperwork for new employees
    b. Quarterly specimen kit audit reports
    c. Validation plan before a new method or test is evaluated or an archived test is reinstated
    d. Validation reports /summaries before a new method or test is implemented or an archived test is reinstated
    e. New Test checklist
    f. SOPs – new and revised
    g. Corrective actions generated by the Lab Director and/ or Supervisor following the review of problems logs, QC charts, equipment maintenance

Proposed action items from this meeting:

1. **By March 2:** Directors must review the Personnel Lists to ensure that there is at least one qualified Technical Supervisor for each Specialty area in each Laboratory grouping. Revise the Personnel lists as appropriate.

2. **The week of March 5:** Schedule a follow up meeting with Directors to get feedback on the transition plan before we move forward. We already have room 863 reserved for the former monthly QA/QC meetings.

3. Propose to do this same presentation for all staff after March 21. We would offer 2- 3 sessions at different times over multiple days.

Quality Teams – roles and responsibilities defined

Guidance Team (AKA Quality Council)

Supports the project team's activities, secures resources, and clears a path in the organization
Generally is a group of managers but may include non-managers
Consists of 3 -6 members
- With diverse skills and resources
- All have a stake in the chosen process
- Have authority to make changes in process under study

Team Leader

Runs the team, arranges logistical details, facilitates meeting and so forth
Generally supervisors or managers in the project area, which means they are close to the process and can better guide team members
Leaves rank outside the meeting room, facilitates discussions and only occasionally actively participates
Contact point for communication between team and the rest of the organization, including guidance team
Official keeper of the team records
Is a full fledged team member

Quality Advisor

Person trained in scientific approach and in working with groups, who helps keep the team on track and provides training as needed
Generally have training in project management, group process, statistics and the scientific tools
Job is to help team members discover for themselves what the answers are, not dictate answers to the rest of the team
Outsider to the team and can maintain a neutral position

Focus of Quality Advisor:

Observe the team's progress, evaluating how the team functions, and use these observations to help the team improve its process
Instruct team members in the scientific tools, and help to guide the team's effort when technical expertise is needed
Except when teaching the team about scientific tools, or helping team get unstuck during a meeting, the quality advisor works primarily before and after the meeting in conference with the team leader

Project Team Members - typically up to five members

The people who form the bulk of the team, who carry out assignments and make improvements
Appointed by the guidance team
Usually people who work closely with some aspect of the process under study
Often representing different stages of the process and groups likely to be affected by the project
Can be of various ranks, professions, classifications, or work areas
Should consider the project now part of their job
Responsible for contributing as fully to the project as possible, sharing their knowledge and expertise
Participate in all meetings and discussions
Complete assignments between meetings

Prepared by Peggy DiNatale 2/13/07

Can the two approaches work together?

Yes

Systematic Approach is most constructive

1. Review regulations and their specific documentation requirements – must continue to meet accreditation criteria
2. Look at current practices of QA and available documentation (meeting minutes, # times SOPs are submitted before QA approves, problem logs, corrective actions, accreditation reports)
3. Quantify how many defects were identified by each QA activity
4. Quantify how many practices have been routinely adopted by the Laboratory Supervisors, without prompting by QA
5. Management reports to ID problems common across multiple labs
6. Define process or forum for different levels of staff to discuss:
   a. areas of concern
   b. process improvements
7. Standardize, via SOPs, tasks that are common to most of the laboratories

QI Data collection tools:
Deployment chart
Work flow diagram
Pareto chart analysis
Process flow diagram

Prepared by Peggy DiNatale 2/13/07

Quality Assurance:

Ensure a quality or defect free product

Management of quality assurance is generally from top down

Responsibility or ownership of quality generally defaults to Director and/or Manager of Department or QA Department

Communication channels vary based on management style and organization chart

Tools for decision making vary based on management style and organization chart

Activities are generally based on meeting regulatory requirements

Quality Improvement:

Ensure a defect free **process to produce** a quality product

Teams are formed to describe process, identify steps in process where problems occur, change process to eliminate or improve problem steps in process

Responsibility or ownership of quality belongs to the members of the team or department

Communication channels start at team level and are disseminated to all staff

Tools for decision making are based on a input from people involved in the process at all levels and are based on a scientific approach through the use of data collection and analysis

Methodical approach to problem identification and problem solving; takes time; not a quick fix; generally provides a better long term improvement; decreases chance for repeating defects

Prepared by Peggy DiNatale 2/13/07

Quality Improvement Approach

Define your products

Requisition form, test reports, proficiency result, test results, waste, media, reagents, letters, and worksheets

Define the process for each product

Written process and actual process must match

Initially, a team or department will identify several different versions of one process – must standardize

Collect data before changes are considered

Data will direct you to the area that requires attention and will have the biggest impact and sustained, improved quality

80% of the trouble comes from 20% of the problems

Data collection tools:

- Flowcharts (steps in process; work flow; deployment chart)
- Pareto charts
- Cause and Effect Diagrams
- Operational Definitions
- Stratification and Is/Is-Not analysis
- Time plots
- Control charts
- Dot Plots and Stem-and-Leaf Displays
- Checksheets
- Scatter Diagrams

Tools for making Decisions

- Brainstorming
- Multivoting
- Nominal Group Technique

Prepared by Peggy DiNatale 2/13/07